LISTING OF CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the Application.

1-9. (Canceled).

10. (Previously presented) A method of forming a lesion in a tissue structure, comprising the steps of:

positioning an inflatable cryogenic element on the tissue structure with a temperature sensor between a portion of the inflatable cryogenic element and a portion of the tissue surface;

supplying cryogenic fluid to the inflatable cryogenic element;

maintaining pressure within the inflatable cryogenic element below about 100 mm Hg; and

measuring tissue temperature with the temperature sensor.

11. (Original) A method as claimed in claim 10, wherein the step of positioning an inflatable cryogenic element comprises positioning an inflatable cryogenic element carried on a distal portion of a surgical probe on the tissue structure with a temperature sensor carried on an exterior surface of the inflatable cryogenic element between a portion of the inflatable cryogenic element and a portion of the tissue surface.

12. (Original) A method as claimed in claim 10, wherein the step of supplying cryogenic fluid comprises supplying cryogenic liquid to the inflatable cryogenic element.

13. Canceled.

14. (Original) A method as claimed in claim 10, wherein the step of positioning an inflatable cryogenic element comprises positioning an inflatable cryogenic element on an epicardial surface with a temperature sensor between a portion of the inflatable cryogenic element and a portion of the epicardial surface.

15-20. Canceled.

21. (Currently Amended) A method of forming a lesion in a tissue structure, comprising the steps of:

positioning a resilient inflatable cryogenic element on the tissue structure with a surgical probe;

inflating the resilient inflatable cryogenic element with cryogenic fluid; and

maintaining pressure within the resilient inflatable cryogenic element below about 100 mm Hg, wherein the step of positioning a resilient inflatable cryogenic element comprises positioning a resilient inflatable cryogenic element on an epicardial surface with a temperature sensor between a portion of the resilient inflatable cryogenic element and a portion of the epicardial surface.

22. (Original) A method as claimed in claim 21, wherein the step of inflating the resilient inflatable cryogenic element comprises inflating the resilient inflatable cryogenic element with cryogenic liquid.

23. (Original) A method as claimed in claim 21, wherein the step of inflating the resilient inflatable cryogenic element comprises inflating the resilient inflatable cryogenic element with cryogenic liquid by way of an infusion lumen defining a first cross-sectional area, the method further comprising the step of: ventilating the cryogenic liquid from the resilient inflatable cryogenic element by way of a ventilation lumen defining a second cross-sectional area, the second cross-sectional area being greater than the first cross-sectional area.

24-26. (Canceled).

27. (Previously Amended) A surgical probe, comprising:

a relatively short shaft defining a distal portion and a proximal portion;

an inflatable cryogenic element, defining an exterior surface, associated with the distal portion of the shaft; and

at least one temperature sensor on the exterior of the inflatable cryogenic element, wherein the relatively short shaft is between about 3 cm and about 12 cm.

28. (Previously Amended) A surgical probe, comprising:

a relatively short shaft; and

a resilient inflatable cryogenic element carried by the relatively short shaft and configured to operate at a maximum internal pressure of about 100 mm Hg, wherein the resilient inflatable cryogenic element has a burst pressure rating of about 760 mm Hg.

REMARKS

Claims 10-12, 14, 21-23, 27 and 28 are pending in the application. Claim 21 is currently amended. The amendments to the claims do not present any new matter. Claim 24 is canceled without prejudice. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Allowed Claim

Applicant kindly acknowledges that claim 28 is allowed. Office Action (p. 5).

II. Claims 10, 12 and 21-23 Are Novel Over Droegemueller

Independent claims 10 and 21 and respective dependent claims 11, 12, 22 and 23 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 3,924,628 to Droegemueller (hereafter referred to as "Droegemueller"). To anticipate a claim, a reference must disclose each and every limitation of the claim. Applicant respectfully traverses the rejection.

Droegemueller fails to disclose, teach or suggest "positioning an inflatable cryogenic element on the tissue structure with a temperature sensor between a portion of the inflatable cryogenic element and a portion of the tissue surface" as recited in claim 10 and "positioning a resilient inflatable cryogenic element on an epicardial surface with a temperature sensor between a portion of the resilient inflatable cryogenic element and a portion of the epicardial surface" as recited in claim 21.

It is alleged in the Office Action that the "inflatable cryogenic element" as recited in the claims is the bladder 11 described by Droegemueller, and the "temperature sensor" as recited in the claims is the thermocouple 50 described by Droegemueller and illustrated in Fig. 1A, which is a partial sectional view taken along line 1a-1a of Fig. 1. Droegemueller, however, explains that the thermocouple 50 is placed "in the bladder." Droegemueller (col. 6, lines 30-31). More specifically, Fig. 1A of Droegemueller illustrates the thermocouple 50 embedded within the wall

of the bladder 11. Droegemueller further explains that the reason the thermocouple 50 is embedded or positioned within the bladder in this manner is that thermocouples 50 and their leads are placed between successive layers of bladder material as the bladder is formed. Droegemueller (col. 6, lines 30-33). Consequently, Droegemueller fails to disclose positioning an inflatable cryogenic element on the tissue structure with a temperature sensor between a portion of the inflatable cryogenic element and a portion of the tissue surface" as recited in claim 10 and "positioning a resilient inflatable cryogenic element on an epicardial surface with a temperature sensor between a portion of the resilient inflatable cryogenic element and a portion of the epicardial surface" as recited in claim 21 since the thermocouple is embedded within layers of the bladder 11 and does not contact tissue.

Further, Applicant notes that claims 10 and 21 recite *inter alia* "maintaining pressure within the inflatable cryogenic element below about 100 mm Hg." Droegemueller, however, refers to pressures greater than 100mm Hg. Specifically, Droegemueller explains that the bladder should be inflated to a pressure sufficient to insure firm contact but should preferably be maintained at about 2 psi (103 mm Hg) or 3 psi (155 mm Hg) to avoid risk of internal injury. Droegemueller (col. 3, lines 58-68). Droegemueller does not otherwise disclose lower pressures or explain by what extent pressures can be reduced while still providing sufficient pressure to insure firm contact with tissue. Droegemueller (col. 3, lines 58-59).

Additionally, Droegemueller fails to disclose, teach or suggest "wherein the step of positioning a resilient inflatable cryogenic element comprises positioning a resilient inflatable cryogenic element on an epicardial surface with a temperature sensor between a portion of the resilient inflatable cryogenic element and a portion of the epicardial surface" as recited in claim 21. In contrast, Droegemueller describes inserting a probe and an attached bladder into a uterus

and destroying the functional lining of the uterus for purposes of female sterilization. Droegemueller (col. 1, lines 6-15; col. 2, lines 1-39; col. 3, lines 54-62).

Therefore, Applicant respectfully submits that Droegemueller does not anticipate independent claims 10 and 21 in view of the above remarks and deficiencies of the cited reference. Dependent claims 12, 22 and 23 incorporate the elements and limitations of respective independent claims 10 and 21 and, therefore, are also believed novel over Droegemueller.

Further, Droegemueller fails to disclose, teach or suggest "wherein the step of inflating the resilient inflatable cryogenic element comprises inflating the resilient inflatable cryogenic element with cryogenic liquid by way of an infusion lumen defining a first cross-sectional area, the method further comprising the step of: ventilating the cryogenic liquid from the resilient inflatable cryogenic element by way of a ventilation lumen defining a second cross-sectional area, the second cross-sectional area being greater than the first cross-sectional area" as recited in claim 23. It is alleged in the Office Action that the "supply tube 22" is the "infusion lumen" as recited in claim 23, and the return tube 25 is the "ventilation lumen" as recited in claim 23. Droegemueller explains that during use, nitrogen fluid emerges into bladder 11, forcing it to expand. Cold nitrogen gas absorbs heat from the bladder 11 and flows through ports 24 into return tube 25 and is vented to the atmosphere at the open end 26 of the tube 25. Droegemueller (col. 3, lines 29-35). Thus, Droegemueller explains that nitrogen gas (rather than a cryogenic liquid) flows through the ports, into the return tube 25, and is vented into the atmosphere. Accordingly, Droegemueller does not anticipate claim 23, which recites ventilating cryogenic liquid by way of a ventilation lumen.

In view of the above remarks, Applicant respectfully request the rejection of claims 10, 12 and 21-23 under 35 U.S.C. §102(b) be withdrawn.